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10/570,734	10/18/2006	Fernando Albericio Palomera	13566.105010	7206

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EXAMINER	
NIEBAUER, RONALD T	

ART UNIT	PAPER NUMBER
1654	

NOTIFICATION DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

usptomailnyc@kslaw.com

Office Action Summary	Application No.	Applicant(s)	
	10/570,734	PALOMERA ET AL.	
	Examiner	Art Unit	
	RONALD T. NIEBAUER	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 June 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,9,10,12,13 and 15-25* is/are pending in the application.

4a) Of the above claim(s) *24 and 25* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,9,10,12,13 and 15-23* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *3/6/06, 4/4/07, 9/18/07, 3/11/09, 3/11/09, 6/19/09*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicant's election with traverse of Group 1 (claims 1,9-10,12-13,15-23) and the following species: [Nε(Me)3-Lys8,(4S)-MeHex14]-KF (compound 93 disclosed in example 10) in the reply filed on 6/19/09 is acknowledged. The traversal is on the ground(s) that the claims define a special technical feature over the prior art. Applicants argue that the Macia thesis compound is different since it is linked to a resin, lacks the amino acids as positions 2 and 3, lacks a ring system, and is modified at various positions. Applicants argue that there is no burden in the searching. Applicants argue that chemical compounds routinely cover large number of compounds.

Applicants arguments have been considered but are not found persuasive.

Although Applicants argue that the Macia thesis compound is different, it is noted that the instant specification (page 19 first complete paragraph) defines compound to include, for example, pharmaceutically active derivatives which are described as capable of providing a residue of the compound. In the instant case, Macia PhD thesis (see the 2nd npl citation of IDS dated 3/11/09) teach in section 3.2.2.2 kahalalide F compounds in which L-Orn8 has a protecting group (i.e. Boc). Such compounds meet the limitations of the instantly claimed compounds which include derivatives which include a residue. For example, L-Orn8 is a residue. Thus, the technical features are not a contribution over the prior art and the claims lack unity

Although applicants argue that there is no burden in the searching, it is noted that the instant specification (page 19 first complete paragraph) defines compound to include, for example pharmaceutically active derivatives which are described as capable of providing a

residue of the compound. Thus the genus includes many compounds. The search for the compounds requires employing different search queries and/or the prior art applicable to one compound would not likely be applicable to another compound.

The requirement is still deemed proper and is therefore made FINAL.

Claims 2-8,11,14 have been cancelled.

Claims 24-25 are to a non-elected group.

Claims 24-25 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 6/19/09.

The elected species was found to be free of the prior art. However, since no claim reads solely on the elected species no claim is indicated as allowable. In accord with section 803.02 of the MPEP, the search was extended to other species. As discussed below art was found on other species that read on the instant claims.

Claims 1,9-10,12-13,15-23 are under consideration.

Information Disclosure Statement

The information disclosure statement (IDS) submitted on 3/6/06 has been considered by the examiner.

The information disclosure statement (IDS) submitted on 4/4/07 has been considered by the examiner.

The information disclosure statement (IDS) submitted on 9/18/07 has been considered by the examiner.

The information disclosure statement (IDS) submitted on 3/11/09 and entitled 'Related Case Submission' has been considered by the examiner.

The information disclosure statement (IDS) submitted on 6/19/09 has been considered by the examiner.

The information disclosure statement filed 3/11/09 and entitled 'Information disclosure statement by applicant' fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each cited foreign patent document; each non-patent literature publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein has not been considered.

The 4th entry of the NPL section is Carlos Jimenez Garcia Ph. D. Thesis. However, the thesis is not in the English language and no translation has been provided for this thesis. The MPEP section 609.04(a) III states that "Each information disclosure statement must further include a concise explanation of the relevance, as it is presently understood by the individual designated in 37 CFR 1.56(c) most knowledgeable about the content of the information listed that is not in the English language." No such explanation has been provided for the 4th entry of the NPL section (Carlos Jimenez Garcia Ph. D. Thesis).

Specification

The disclosure is objected to because of the following informalities:

Section 606 of the MPEP states: "Inasmuch as the words >"new,"< "improved," "improvement of," and "improvement in" are not considered as part of the title of an invention, these words should not be included at the beginning of the title of the invention and will be deleted when the Office enters the title into the Office's computer records, and when any patent issues." In the instant case, the first word of the title is 'New' which is improper.

37 CFR 1.52(b)(5) states: "Other than in a reissue application or reexamination proceeding, the pages of the specification including claims and abstract must be numbered consecutively, starting with 1, the numbers being centrally located above or preferably below, the text." In the instant case, the pages of the specification have not been numbered.

The last entry in the tables on pages 39,42 appears to be cut-off such that the identity of the analogue is unclear. The tables on pages 62-80 appear to use commas in numerous locations where it seems that periods would be appropriate. For example, the first entry on page 62 is 3,27E-07. It would seem that 3.27E07 is the appropriate entry.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 21 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 21 refers to '(4RS)-MeHex. With respect to '(4RS)-MeHex', the specification sets forth the meaning of the abbreviation MeHex (page 15). Although the art recognizes 'R' and 'S' stereochemistry notations, for example (4R)-MeHex and (4S)-MeHex, the notation (4RS) is unclear. It is unclear if the stereochemistry is classified as R or S. It is unclear if 'RS' indicates that there can be either R or S or if the intent is that there is a combination of R and S. As such, there is more than one reasonable interpretation of the claims.

Claim 21 refers to 'Pfh'. The specification defines the abbreviation 'Phf-OH' (page 15). However, Pfh is not necessarily the equivalent of Phf. It is unclear is there is a typographical error or if Pfh is to designate or represent some other compound. Since amino acids are also known to be represented by single letter abbreviations, it is unclear if Pfh is ProPheHis. As such, there is more than one reasonable interpretation of the claims.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1,9-10,12-13,15-23 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the

relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The MPEP states that the purpose of the written description requirement is to ensure that the inventor had possession, as of the filing date of the application, of the specific subject matter later claimed by him. The courts have stated:

> "To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention." Lockwood v. American Airlines, Inc., 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (Fed. Cir. 1997); In re Gostelli, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) ("[T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." Lockwood, 107 F.3d at 1572, 41 USPQ2d at 1966." Regents of the University of California v. Eli Lilly & Co., 43 USPQ2d 1398.

Further, for a broad generic claim, the specification must provide adequate written description to identify the genus of the claim. In *Regents of the University of California v. Eli Lilly & Co.* the court stated:

> "A written description of an invention involving a chemical genus, like a description of a chemical species, 'requires a precise definition, such as by structure, formula, [or] chemical name,' of the claimed subject matter sufficient to distinguish it from other materials." *Fiers*, 984 F.2d at 1171, 25 USPQ2d 1601; *In re Smythe*, 480 F.2d 1376, 1383, 178 USPQ 279, 284985 (CCPA 1973) ("In other cases, particularly but not necessarily, chemical cases, where there is unpredictability in performance of certain species or subcombinations other than those specifically enumerated, one skilled in the art may be found not to have been placed in possession of a genus …") *Regents of the University of California v. Eli Lilly & Co.*, 43 USPQ2d 1398.

The MPEP further states that if a biomolecule is described only by a functional characteristic, without any disclosed correlation between function and structure of the sequence, it is "not sufficient characteristic for written description purposes, even when accompanied by a method of obtaining the claimed sequence." MPEP § 2163. The MPEP does state that for a

generic claim the genus can be adequately described if the disclosure presents a sufficient number of representative species that encompass the genus. MPEP § 2163. If the genus has a substantial variance, the disclosure must describe a sufficient variety of species to reflect the variation within that genus. See MPEP § 2163. Although the MPEP does not define what constitute a sufficient number of representative species, the courts have indicated what do not constitute a representative number of species to adequately describe a broad generic. In *Gostelli*, the courts determined that the disclosure of two chemical compounds within a subgenus did not describe that subgenus. *In re Gostelli*, 872, F.2d at 1012, 10 USPQ2d at 1618.

The MPEP lists factors that can be used to determine if sufficient evidence of possession has been furnished in the disclosure of the Application. These include "level of skill and knowledge in the art, partial structure, physical and/or chemical properties, functional characteristics alone or coupled with a known or disclosed correlation between structure and function, and the method of making the claimed invention. Disclosure of any combination of such identifying characteristics that distinguish the claimed invention from other materials and would lead one of skill in the art to the conclusion that the applicant was in possession of the claimed species is sufficient." MPEP § 2163. While all of the factors have been considered, a sufficient amount for a *prima facie* case are discussed below.

Further, to provide evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to be considered include: a) the scope of the invention; b) actual reduction to practice; c) disclosure of drawings or structural chemical formulas; d) relevant identifying characteristics including complete structure, partial structure, physical and/or chemical properties, and structure/function

correlation; e) method of making the claimed compounds; f) level of skill and knowledge in the art; and g) predictability in the art.

In the instant case, the claims are drawn to compounds.

Although unclear (see 112 2nd) the claims have been given the broadest reasonable interpretation such that (RS) can be any combination of R and S and such that Pfh is Phf. The instant specification (page 19 first complete paragraph) defines compound to include, for example, pharmaceutically active derivatives which are described as capable of providing a residue of the compound. Thus, the compounds as claimed include the derivatives as defined on page 19. Thus, compounds which include a residue of the compounds of the claims are also within the scope of the claims.

(1) Level of skill and knowledge in the art/predictability in the art:

The level of skill in the art is high. There is unpredictability in predicting functional effects of replacements. It is not within the skill of the art to predict any and all derivatives,prodrugs, and residues that would result in compounds in which the resulting compound is an antitumor compound.

(2) Scope of the invention/Partial structure/disclosure of drawings:

In the instant case, the claims are drawn to compounds. Although unclear (see 112 2nd) the claims have been given the broadest reasonable interpretation such that (RS) can be any combination of R and S and such that Pfh is Phf. The instant specification (page 19 first complete paragraph) defines compound to include, for example, pharmaceutically active derivatives which are described as capable of providing a residue of the compound. Thus, the

compounds as claimed include the derivatives as defined on page 19. Thus, compounds which include a residue of the compounds of the claims are also within the scope of the claims. In considering the size of the genus, if any 10 of the 14 positions of the compound shown in claim 1 were replaced with any of the 20 naturally occurring amino acids (i.e. derivatives) there are at least 20^{10} (i.e. 10240000000000) different compounds. Further, there are many other compounds possible with non-natural amino acids or compounds that are fragments that are within the scope of the claims.

Although claim 1 recites a compound, the claims are not limited to that compound since the compounds are defined to include derivatives. The claims do not require a significant structural core. A single residue of the compound is not a significant structural core.

The specification, for example, Table VI and claim 15 recites numerous specific compounds, however the compounds represent a small fraction of the possible variety of compounds in the genus. The compounds shown in the examples appear to be limited to modifications at position 8 and 14. However, the specification (page 19 first complete paragraph) defines compound to include, for example, pharmaceutically active derivatives which are described as capable of providing a residue of the compound. One of skill in the art would not recognize that applicant was in possession of the claimed genus.

There is substantial variability in the genus. Since there are a substantial variety of componds possible within the genus, the examples do not constitute a representative number of species and do not sufficiently describe the genus claimed (see Gostelli above).

(3) Physical and/or chemical properties and (4) Functional characteristics:

The title of the application states that the compounds are antitumor compounds. However, there is no specific disclosed correlation between structure and function. It is unclear what structural elements are required for the recited function. The specification (page 19 first complete paragraph) defines compound to include, for example, pharmaceutically active derivatives which are described as capable of providing a residue of the compound. It is unclear which residue, if any, is adequate and sufficient to render the compound antitumor. There are no common attributes or characteristics that identify the compounds. As such, one of skill in the art would not recognize a core structure, common attributes, or features of the compounds. One of skill in the art would not recognize compounds outside of those specifically identified. The teaching in the specification appears to be limited to modifications at positions 8 and 14. It is unclear how to extrapolate possible modifications at positions 8 and 14 to the other positions of the compound.

In particular, no common core sequence is taught. One of skill in the art would reasonably conclude that the disclosure fails to provide a representative number of species to describe the genus and that there is a lack of the knowledge in the art regarding which amino acids can vary to maintain the function and thus that the applicant was not in possession of the claimed genus.

(5) Method of making the claimed invention/actual reduction to practice:

The specification (see the examples) describes the making of compounds. However, such compounds are not representative of the instant genus which includes derivatives, nor do the

compounds provide a specific correlation between structure and function such that one could identify any and all antitumor compounds.

As stated *supra*, the MPEP states that written description for a genus can be achieved by a representative number of species within a broad generic. It is unquestionable that claim(s) 1,9-10,12-13,15-23 is/are broad and generic, with respect to all possible compounds encompassed by the claims. The possible structural variations are many. Although the claims may recite some functional characteristics, the claims lack written description because there is no specific disclosure of a correlation between function and structure of the compounds beyond those compounds specifically disclosed in the examples in the specification. Moreover, the specification lacks sufficient variety of species to reflect this variance in the genus. While having written description of compounds identified in the specification tables and/or examples, the specification does not provide sufficient descriptive support for the myriad of compounds embraced by the claims.

The description requirement of the patent statue requires a description of an invention, not an indication of a result that one might achieve if one made that invention. See *In re Wilder*, 736, F.2d 1516, 1521, 222 USPQ 369, 372-73 (Fed. Cir. 1984) (affirming rejection because the specification does "little more than outlin[e] goals appellants hope the claimed invention achieves and the problems the invention will hopefully ameliorate.") Accordingly, it is deemed that the specification fails to provide adequate written description for the genus of the claims and does not reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the entire scope of the claimed invention.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1,9-10,12-13,15-23 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

Albericio teach that kahalalide F is a cyclic depsipeptide isolated from *Elysia rufescens*. On page 2, Albericio show the structure of kahalalide F. The instant specification (page 19 first complete paragraph) defines compound to include, for example, pharmaceutically active derivatives which are described as capable of providing a residue of the compound. Thus, the compounds as claimed include the derivatives as defined on page 19. Thus, compounds which include a residue of the compounds of the claims are also within the scope of the claims. Kahalalide F as shown on page 2 of Albericio also meet the claim limitation of compound since the compound includes a residue, for example Phe (see position 3) of the compounds as claimed. Since the compound is present in *Elysia rufescens* it is present in a composition as recited in claim 23.

Although unclear (see 112 2nd) the claims have been given the broadest reasonable interpretation such that (RS) can be any combination of R and S and such that Pfh is Phf.

There is no indication that the compounds of the current invention have been isolated or removed from a naturally occurring environment. The claimed subject matter therefore reads on a product of nature.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1,9-10,12-13,15-23 are rejected under 35 U.S.C. 102(b) as being anticipated by Albericio et al (WO 01/58934, cite 1 of IDS 3/6/06).

Albericio teach kahalalide F compounds and mimics thereof (abstract, claims). On page 2, Albericio show the structure of kahalalide F. In example 6 (page 31) Albericio teach the compound 5-MeHex-D-Val-Thr(tBu)-Val-D-Val-D-Pro-Orn(Boc)-D-allo-Ile-D-allo-Thr(Val-Z-Dhb-Phe-H)-D-allo-Ile-D-Val-OH. In the Table on pages 60-63 Albericio teach a variety of other compounds. Albericio teach pharmaceutical compositions of the compounds (page 16 last 2 paragraphs; claim 9). It is noted that claims 1,9-10,12-13,15-22 all refer to a compound. The instant specification (page 19 first complete paragraph) defines compound to include, for example, pharmaceutically active derivatives which are described as capable of providing a residue of the compound. Thus, the compounds as claimed include the derivatives as defined in page 19. Thus, compounds which include a residue of the compounds of the claims are also within the scope of the claims. As such, compounds taught by Albericio such as 5-MeHex-D-Val-Thr(tBu)-Val-D-Val-D-Pro-Orn(Boc)-D-allo-Ile-D-allo-Thr(Val-Z-Dhb-Phe-H)-D-allo-Ile-D-Val-OH (example 6 page 31) meet the claim limitation of being a compound since the compound includes a residue, for example Phe (see position 3), of the compounds as claimed.

Thus the limitations of claims 1,9-10,12-13,15-23 are met. Further, Albericio teach pharmaceutical compositions of the compounds (page 16 last 2 paragraphs; claim 9) as recited in claim 23. Further, kahalalide F as shown on page 2 of Albericio also meet the claim limitation of compound since the compound includes a residue, for example Phe (see position 3) of the compounds as claimed. It is noted that Albericio teach that alternatives to ornithine include lysine (page 15 2nd complete paragraph).

Although unclear (see 112 2nd) the claims have been given the broadest reasonable interpretation such that (RS) can be any combination of R and S and such that Pfh is Phf.

Claims 1,9-10,12-13,15-23 are rejected under 35 U.S.C. 102(b) as being anticipated by Angel Lopez Macia PhD thesis (Jan 18 2001, see the 2nd npl citation of IDS dated 3/11/09).

Macia teach methods of synthesizing kahalalide F (page 4). In section 3.2.2.2 (page 7) Macia teach the compound 5-MeHex-Val-Thr(tBu)-Val-Val-Pro-Orn(Boc)-Ile-Thr(Val-Fmoc)-Ile-Val-ClTrt-PS. It is noted that claims 1,9-10,12-13,15-22 all refer to a compound. The instant specification (page 19 first complete paragraph) defines compound to include, for example, pharmaceutically active derivatives which are described as capable of providing a residue of the compound. Thus, the compounds as claimed include the derivatives as defined in page 19. Thus, compounds which include a residue of the compounds of the claims are also within the scope of the claims. As such, compounds taught by Macia such as 5-MeHex-Val-Thr(tBu)-Val-Val-Pro-Orn(Boc)-Ile-Thr(Val-Fmoc)-Ile-Val-ClTrt-PS (section 3.2.2.2 page 7) meet the claim limitation of being a compound since the compound includes a residue, for example Val (see position 11), of the compounds as claimed. Further, Macia teach the synthesis (page 28 section 3.2.3.5.2) and

purification (Figure 3.29) of KF-1 and KF-2. Since the compounds were purified they were necessarily in a composition as recited in claim 23. Since the compound includes a residue, for example D-Val (see position 13) as the compounds of the instant invention the limitations of claims 1,9-10,12-13,15-23 are met.

Although unclear (see 112 2nd) the claims have been given the broadest reasonable interpretation such that (RS) can be any combination of R and S and such that Pfh is Phf.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1,9-10,12-13,15-23 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-49 of U.S. Patent No. 7,482,429 ('429).

Although the conflicting claims are not identical, they are not patentably distinct from each other.

‘429 teach compounds including (claim 1) 5-MeHex-D-Val-Thr-Val-D-Val-D-Pro-Orn-D-allo-Ile-cyclo(D-allo-Thr-D-allo-Ile-Val-Phe-Z-Dhb-Val). The instant specification (page 19 first complete paragraph) defines compound to include, for example, pharmaceutically active derivatives which are described as capable of providing a residue of the compound. Thus, the compounds as claimed include the derivatives as defined in page 19. Thus, compounds which include a residue of the compounds of the claims are also within the scope of the claims. As such, compounds taught by ‘429 such as 5-MeHex-D-Val-Thr-Val-D-Val-D-Pro-Orn-D-allo-Ile-cyclo(D-allo-Thr-D-allo-Ile-Val-Phe-Z-Dhb-Val) (claim 1) meet the claim limitation of being a compound since the compound includes a residue, for example D-Val (see position 13), of the compounds as claimed. Further, ‘429 teach a composition as recited in claim 23. Thus, the limitations of claims 1,9-10,12-13,15-23 are met.

Although unclear (see 112 2nd) the claims have been given the broadest reasonable interpretation such that (RS) can be any combination of R and S and such that Pfh is Phf.

Claims 1,9-10,12-13,15-23 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-13 of copending Application No. 11/587,177 (‘177). Although the conflicting claims are not identical, they are not patentably distinct from each other.

‘177 teach compounds including the compound depicted in claim 3 The instant specification (page 19 first complete paragraph) defines compound to include, for example,

pharmaceutically active derivatives which are described as capable of providing a residue of the compound. Thus, the compounds as claimed include the derivatives as defined in page 19. Thus, compounds which include a residue of the compounds of the claims are also within the scope of the claims. As such, compounds taught by '177 such as the compound depicted in claim 3 meet the claim limitation of being a compound since the compound includes a residue, for example D-Val (see position 13), of the compounds as claimed. Further, since '177 teach the synthesis of the compounds the compounds would be in a composition as recited in claim 23. Thus, the limitations of claims 1,9-10,12-13,15-23 are met.

Although unclear (see 112 2nd) the claims have been given the broadest reasonable interpretation such that (RS) can be any combination of R and S and such that Pfh is Phf.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims are directed to an invention not patentably distinct from claims of commonly assigned U.S. Patent No. 7,482,429 and Application No. 11/587,177 as discussed above.

The U.S. Patent and Trademark Office normally will not institute an interference between applications or a patent and an application of common ownership (see MPEP Chapter 2300). Commonly assigned U.S. Patent No. 7,482,429 and Application No. 11/587,177, discussed above, would form the basis for a rejection of the noted claims under 35 U.S.C. 103(a) if the commonly assigned case qualifies as prior art under 35 U.S.C. 102(e), (f) or (g) and the conflicting inventions were not commonly owned at the time the invention in this application was made. In order for the examiner to resolve this issue, the assignee can, under 35 U.S.C.

103(c) and 37 CFR 1.78(c), either show that the conflicting inventions were commonly owned at the time the invention in this application was made, or name the prior inventor of the conflicting subject matter.

A showing that the inventions were commonly owned at the time the invention in this application was made will preclude a rejection under 35 U.S.C. 103(a) based upon the commonly assigned case as a reference under 35 U.S.C. 102(f) or (g), or 35 U.S.C. 102(e) for applications pending on or after December 10, 2004.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to RONALD T. NIEBAUER whose telephone number is (571)270-3059. The examiner can normally be reached on Monday-Thursday, 7:30am-5:00pm, alt. Friday, EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Anish Gupta/
Primary Examiner, Art Unit 1654

/Ronald T Niebauer/
Examiner, Art Unit 1654